Section 6.0 510(k) Summary

510(k) Summary

Submitter: Clinical Innovations, Inc.
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Proprietary Names:	Latitude Esophageal Motility Study Pressure Catheter and Latitude Ano-Rectal Pressure Catheter
Common/Usual Name:	Gastrointestinal Pressure Catheter
Classification Name:	System, Gastrointestinal Motility (Electrical)

The legally marketed devices to which equivalence is claimed are the Konigsberg Esophageal Solid State Catheter and the Medtronic Zinetics AMS Anorectal Catheter.

Description of the device: Gastrointestinal pressure catheters with pressure-sensing membrane cavities along the length of the catheter and a port for balloon inflation for the Anorectal model. This product is non-sterile, single patient use catheter. The system includes reusable cables with reusable pressure transducers.

Intended use: This catheter is for use on patients requiring esophageal and ano-rectal pressure monitoring.

The Latitude Pressure Catheters are substantially equivalent to the predicate devices because:

- they have the same intended uses, namely, esophageal and ano-rectal pressure measurement, and
- they have the same basic technological characteristics as predicate devices, namely, pressure sensors located along the length of the catheter,
- markings for catheter insertion,
- port and lumen for Anorectal balloon inflation, and
- external zeroing of pressure.

They use the same or similar materials, all of which have been shown to be biocompatible and to function well in the intended application.

The safety and effectiveness are similar to existing devices as demonstrated in the laboratory testing. Biocompatibility testing shows that the materials used in the Latitude Pressure Catheters are safe for this application. Effectiveness is the same as the

predicate devices. The laboratory testing verified the performance in terms of sensor accuracy, mechanical integrity, and overall performance.

Wm. Dean Wallace, M.D., Ph.D.

10-7-02
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 0 7 2003

Wm. Dean Wallace, M.D., Ph.D.
President
Clinical Innovations
747 West 4170 South
MURRAY UTAH 84123

Re: K022023
Trade/Device Name: Latitude Esophageal Pressure Catheter (Model #GIM-6000E) and Latitude Ano-Rectal Pressure Catheter (Model # GIM-6000A)
Regulation Number: 21 CFR §876.1725
Regulation Name: Gastrointestinal motility monitoring system
Regulatory Class: Class II
Product Code: 78 KLA
Dated: October 7, 2002
Received: October 9, 2002

Dear Dr. Wallace:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

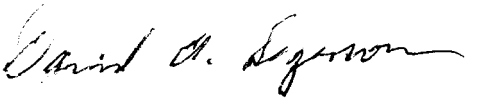
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

10.0 Indications For Use

Device Name: Latitude Esophageal Pressure Catheter (Model number GIM-6000E) and Latitude Ano-Rectal Pressure Catheter (Model number GIM-6000A)

510(k) Number: K022023

Indications for use: These catheters are for use on patients requiring gastrointestinal manometry testing. The Esophageal Pressure Catheter Model number GIM-6000E is for use with esophageal motility studies. The Ano-Rectal Pressure Catheter Model number GIM-6000A is for use in ano-rectal pressure studies.

(PLEASE NO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Segerman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K022023

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)